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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,822	08/22/2003	Nickolai Alexandrov	2750-1571P	7309
2292 7590 11/12/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
BUL PHUONG T				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
11/12/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/645,822

**Applicant(s)**

ALEXANDROV ET AL.

**Examiner**

Phuong T. Bui

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 6-20 is/are pending in the application.
- 4a) Of the above claim(s) 11,12,15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-10,13,14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's restriction election filed September 7, 2010. Applicant elected Invention I, drawn to a nucleic acid molecule and method of transformation without traverse. Claims 1-20 are pending. Claims 11, 12, 15 and 16 are withdrawn from examination as being drawn to nonelected inventions. Claims 1, 2, 6-10, 13, 14 and 17-20 to the extent of SEQ ID NO:16117 encoding SEQ ID NO:16118 are examined in the instant application. The restriction is made FINAL.

SEQ ID NO:16117 encoding SEQ ID NO:16118 was first disclosed in the instant application, filed August 22, 2003.

### ***Drawings***

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted are informal drawings not acceptable for publication (Fig. 5, for example, is not legible). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Objections***

3. The specification is objected to because the specification discloses sequences which are not in compliance with 37 CFR 1.821-1.825. SEQ ID NO. identifiers are required for these sequences. For examples, see pages 895, 896, 900, 901 and 909.

Claims 1 and 2 are objected to because they recite nonelected inventions.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, it is unclear whether the recitations in parentheses are intended to be claim limitations.

In claim 1(b), a complementary sequence reads on a 2-mer, which does not appear to be Applicant's intention. It is suggested "fully" be inserted before "complementary".

Claim 1(c) also reads on a 2-mer, which does not appear to be Applicant's intention. It is suggested a function be recited for the hybridized sequence.

In claim 1(c), the metes and bounds of "about" are unclear. It is suggested "about" be deleted.

In claim 2(a), "a fragment thereof" reads on a single base, which does not appear to be Applicant's intention. It is suggested a function be recited for the fragment.

In claim 2(b), "a complement" reads on a 2-mer, and its "fragment thereof" reads on a single base, which does not appear to be Applicant's intention. It is suggested "full-length" be inserted before "complement" and a function be recited for the fragment.

In claim 9, it is suggested "an" be amended to "the" for proper antecedence. See also claim 13.

In claim 10, it is suggested "a vector" be amended to "the vector" for proper antecedence. See also claims 14 and 18.

In claim 17, it is suggested "a nucleic" be amended to "the nucleic" for proper antecedence.

In claim 19, it is suggested "a plant" be amended to "the plant" for proper antecedence. See also claim 20.

Clarification and/correction is required.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility.

The specification discloses SEQ ID NO:16117 was isolated from *Arabidopsis thaliana* but does provide a function or utility for SEQ ID NO:16117. The protein expressed by SEQ ID NO:16117 may have some function in *Arabidopsis*. However, that function is not known or disclosed. It is also not known how SEQ ID NO:16117 can be used to achieve a useful outcome. It is apparent that further research is required before the claimed polypeptide would be of benefit to the public. However, the courts

have decided that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use lacks substantial utility.

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, the claimed invention is not refined and developed to the point where specific and substantial benefit exists, as no guidance is provided as to how SEQ ID NO:16117 should be used to achieve a useful outcome. Accordingly, the claimed invention lacks specific and substantial utility. Since SEQ ID NO:16117 lacks utility, its complementary sequence, sequences which hybridize at 5-10C below the melting temperature, a sequence having 85-95% sequence identity and a fragment thereof also lack utility.

Additionally, there also is no well-established utility for SEQ ID NO:16117. SEQ ID NO:16117 does not have a well-established utility such as antisense, protein expression, antibodies or diagnostic purposes because the sequence does not have utility for the reasons indicated above. Thus, the claimed invention lacks utility under current utility guidelines. (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

Note, because the claimed invention is not supported by a specific, substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

Claims 1, 2, 6-10, 13, 14 and 17-20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific,

substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112, first paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In addition to lacking enablement because the claimed invention lacks utility, the recitations of 85-95% sequence identity, complementary sequence, sequences which hybridize at 5-10C below the melting temperature and a fragment thereof are also not enabled for the following reasons. With regard to 85-95% identity and hybridization at 5-10C below the melting temperature, these recitations encompass unspecified base substitutions, deletions, additions, and/or combinations thereof without any guidance as to what functional activity should be retained. Applicant provides no working example of sequences having 85-95% sequence identity or sequences which hybridizes to SEQ ID NO:16117 at 5-10C below the melting temperature. A sequence which hybridizes to degenerate DNA encoding SEQ ID NO:16118 is the noncoding sequence and also would not hybridize to genomic DNA. Applicant does not teach which region(s) of SEQ

ID NO:16117 must be conserved or can tolerate mutations to retain the undisclosed functional activity. The claims encompass inoperable embodiments but the specification provided no guidance or working example as to how such inoperable embodiments can be readily eliminated without undue experimentation. While one skilled in the art can readily make mutations to SEQ ID NO:16117, further guidance is needed as to what mutations would not abrogate its activity, however such activity is defined. With regard to complementary sequence and a fragment thereof, the claims read on a sequence of 2 bases or a single base, which Applicant has not taught one skilled in the art how to make and use. A 2-mer or a single base would not have any functional activity. Longer sequences for antisense or co-suppression are also not enabled because Applicant does not teach what functional activity would be suppressed. Accordingly, Applicant has not enabled the claimed invention without excessive burden and undue experimentation.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 6, 8-10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (Nature, Vol. 402, pp. 761-768, 16 Dec 1999 (U); sequence alignment Lin et al, UniProt\_201006 Database, Accession Nos. Q8RWV3, O48710, Q94L33, Nature, Vol. 402, pp. 761-768, 16 Dec 1999, see Result 1 (V)). Lin teaches a



nucleic acid sequence encoding an amino acid sequence which has 100% sequence identity to Applicant's SEQ ID NO:16118. Lin also teaches a vector, heterologous promoter, host cell, a method of introducing a nucleic acid into a host cell and a method of transforming. transgenic plant cell, plant, progeny, seed and vegetative tissue. A complementary sequence, a sequence which hybridizes to a sequence encoding SEQ ID NO:16118 and fragment thereof read on a 2-mer, and thus are also anticipated by Lin. Accordingly, Lin anticipates the claimed invention.

12. Claims 1, 2, 6-10, 13, 14 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP1033405, published 06 September 2000, SEQ ID NO:16179 (N, copy not attached because of common inventors)). Alexandrov teaches SEQ ID NO. 16179 which has 100% sequence identity to SEQ ID NO:16117. Alexandrov further teaches a vector, host cell, method of introducing a nucleic acid molecule, method of transforming and plant. Accordingly, Alexandrov anticipates the claimed invention.

#### ***Remarks***

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/  
Primary Examiner, Art Unit 1638